

Remarks

Claims 1-119 are pending in this application. Claims 7-12, 27-55, 62-67, and 83-108 have been withdrawn from consideration as drawn to non-elected subject matter. Therefore, claims 1-6, 13-26, 56-61, 68-82, and 109-119 are currently under consideration.

A Petition for a one-month extension of time and the associated fee are enclosed with this paper.

I. Response to Rejections under 35 U.S.C. § 103

A. Legal Standards under 35 U.S.C. § 103

Before responding directly to the issues raised by the Office Action under Section 103, the legal foundation for sustaining such a rejection will be reviewed. Briefly, an applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. 35 U.S.C. §§ 102, 103. It is the USPTO's duty to issue a patent or establish that the applicant is not entitled to a patent under the law. *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Thus, the initial burden is on the USPTO to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). If no *prima facie* case of obviousness is established, then a rejection

under Section 103 cannot properly be sustained. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). If the USPTO establishes a *prima facie* case of obviousness, then the burden of production shifts to the applicant to provide appropriate rebuttal, although the burden of persuasion always remains with the USPTO. *Id.* Such rebuttal may include arguments, amendments, and/or presentation of objective indicia of nonobviousness. However, such objective indicia are always relevant to a determination of nonobviousness whether or not a *prima facie* case of obviousness has been established. *Stratoflex Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1987). To establish a *prima facie* case of obviousness, the Examiner must show all of the limitations of the claimed invention in the prior art. *In re Ehrreich*, 200 U.S.P.Q. 504, 509-11 (C.C.P.A. 1979). The subject matter of the invention must be considered as a whole and through the eyes of a hypothetical person of ordinary skill, not expert skill, in the relevant art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). References must also be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985).

References may be combined if there is a suggestion, motivation, or incentive in the prior art to make such a combination. *In re Dillon*, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (en banc); *In re Jones*, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992). It is not permissible to use hindsight to pick and choose among isolated teachings in the art after first having read Applicant's application to learn the pattern of the invention. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). Finally, all the facts in evidence are evaluated, and patentability is determined on the totality of the record. *In re Corkill*, 226 USPQ 1005, 1008 (Fed. Cir. 1985). Factual determinations made by the USPTO must be based on a preponderance of the evidence, and legal conclusions must be correct. *In re Caveny*, 226 USPQ 1, 3 (Fed. Cir. 1985).

Pursuant to established legal authority, patentability under 35 U.S.C. § 103 requires a four-step analysis, which involves determining (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed inventions, (3) the level of skill in the art, and (4) the objective evidence of nonobviousness that may have been presented. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 311, 314 (Fed. Cir. 1983). After all of these factors have been considered, the ultimate legal conclusion on the issue of obviousness must be

reached. With the above background in mind the rejections under 35 U.S.C. § 103 will be discussed.

B. Factual and Legal Analysis

1. Claims Rejected over the Feldebrugge Reference

Claims 1-6, 13-16, 22-26, 56-61, 68-71, 77-82, 109-113, and 119 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 3,886,299 ("Feldbrugge").

Feldbrugge discloses dense, substantially unpuffed, fibrous products that simulate the muscle of animals or the flesh of fish. (Abstr.) These fibrous products are made by "feeding a proteinaceous dough through a heated channel of decreasing volume to simultaneously elongate and thermally coagulate the dough and then releasing the compression without forcing the dough through a die while maintaining a pressure drop below 100 psi." (Abstr.) More particularly, Feldbrugge used a Sigma mixer to mix ingredients prior to extrusion in a single screw extruder. (Col. 7, lines 30-31; col. 7, line 67, through col. 8, line 2; col. 8, lines 14-17; col. 8, lines 55-56; col. 9, lines 2-4.) This process involved putting the dough in a heated chamber of decreasing volume. This extrusion process required compression and stretching for fiber formation. It also required the dough to show visible fibers during the mixing stage prior to

extrusion. (Col. 5, lines 8-10 and 22-27.) Moreover, no exit die was used. (Abstr.; col. 2, lines 17-19; col. 3, lines 27-32; col. 7, lines 20-23.)

Applicants respectfully traverse the characterization of Feldebrugge's method as involving "thermoplastic extrusion." Applicants respectfully submit that the process described by Feldbrugge involved simple extrusion. The differences between thermoplastic extrusion and simple extrusion are widely recognized, as described in the following quotations:

(1) "Extrusion is simply the operation of shaping a plastic or dough-like material by forcing it through a restriction or die." M.N. Riaz, Introduction to extruders and their principles, in Extruders in Food Applications 1 (M.N. Riaz, ed., Technomic Publishing Co., Lancaster, PA, 2000).

(2) "Food extrusion has been practiced for over 50 years. Initially its role was limited to mixing and forming Now, the food extruder is considered a high-temperature, short-time bioreactor that transforms a variety of raw ingredients into modified intermediate and finished products." J.M. Harper, Food extruders and their application, in Extrusion Cooking 1 (Mercier, Linko & Harper, eds., American Assoc. Cereal Chemists, St. Paul, MN 1998).

(3) "Extrusion may be defined as forcing a pumpable product through a small opening to shape materials in a designated fashion. . . . A home cookie maker is a simple example of an extruder. . . . In many food extrusion processes, heating and cooking of raw materials occur as they are mixed and formed to produce essentially a finished product in a single operation." D.R. Heldman & R.W. Hartel, Food Extrusion, in Principles of Food Processing 253 (Chapman and Hall, New York 1997).

(4) "Thermoplastic extrusion is the process in which a low-water, powder-like raw material is pressed and heated simultaneously in a shear field, forced through a shaping die, and rapidly hardened by cooling. . . . Three main steps of many food technologies, i.e., mixing of food system components, shaping of a food system and fixing the form and structure of a given food product, can be successively and continuously accomplished within the extruder barrel and at the exit." V.B. Tolstoguzov, Thermoplastic extrusion-the mechanism of the formation of extrudate structure and properties, 70 J. Assoc. Official Analytical Chemists 417, 419-420 (1993).

The last of these definitions distinguishes thermoplastic extrusion from simple extrusion. Feldbrugge should be considered simple extrusion, because (1) mixing was carried out in a mixer,

not in the extruder; and (2) the mixture was not forced through an extrusion die.

Even though U.S. Patent No. 4,338,340 ("Morimoto") referred in 1982 to Feldbrugge as describing thermoplastic extrusion, Feldbrugge did not refer to its own process as thermoplastic extrusion, and the Feldbrugge process would not have been considered to be thermoplastic extrusion at the time the present application was filed due to a changed definition stemming from advances in the type of extruders in use.

Further, Feldbrugge did not disclose or suggest each and every limitation of the presently claimed invention. With respect to claims 1 and 56, Feldbrugge did not disclose a thermoplastic extrusion product containing about 1-80% of food grade protein (or mixture of food grade proteins) and about 20-99% edible polysaccharide, where the food grade protein (or mixture of food grade proteins) comprises at least about 25% by weight of whey protein.

With respect to claims 2 and 57, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising about 15-65% by weight of food grade protein. Similarly, with respect to claims 3 and 58, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising about 16-48% by weight of food grade protein.

With respect to claims 4 and 59, Feldbrugge did not disclose or suggest a thermoplastic extrusion product further comprising up to about 75% by weight of plant proteins, animal proteins, microbial proteins, or mixtures thereof.

With respect to claims 5-6 and 60-61, Feldbrugge did not disclose or suggest the thermoplastic extrusion products of the underlying base claims and intervening claims and further comprising wheat proteins.

With respect to claims 13 and 68, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising at least about 50% by weight of whey protein.

With respect to claims 23-26 and 78-81, Feldbrugge did not disclose or suggest thermoplastic extrusion products wherein the whey protein comprised sweet whey solids, whey protein concentrate, whey protein isolate, or mixtures thereof.

With respect to claim 82, Feldbrugge did not disclose or suggest a thermoplastic extrusion product wherein the whey protein is undenatured.

With respect to claims 109-113 and 119, Feldbrugge did not disclose or suggest a thermoplastic extrusion product containing about 40-100% by weight of a whey protein concentrate and about 0-60% by weight of an edible polysaccharide, where the whey protein concentrate comprises at least about 80% by weight of

protein. Still further, with respect to claim 110, Feldbrugge did not disclose or suggest a thermoplastic extrusion product comprising about 40-99% by weight of whey protein concentrate and about 1-60% by weight of edible polysaccharide.

In view of the above, Applicant respectfully submit that a *prima facie* case of obviousness has not been established for failure to show each and every limitation of the presently claimed invention in the prior art. Accordingly, withdrawal of the rejection is respectfully requested.

2. Claims Rejected over the Combination of the
Feldbrugge and Villagran References

Claims 17, 18, 72, 73, 114, and 115 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldbrugge taken together with U.S. Patent No. 5,366,748 ("Villagran").

The Feldbrugge patent was summarized above. Villagran discloses a method of producing an extruded cereal-grain-based food product. In this process, the extruder is simply a mixer for forming a dough. There is no heating, and there is minimal shear in the extruder. The resulting sheet of dough is then cut into segments and fried (col. 1, lines 65-68). A gum may be added to the dough to prevent toothpacking.

The combination of Feldbrugge and Villagran fails to make up for the deficiencies of the Feldbrugge reference alone. That is, claims 17-18, 72-73, and 114-115 are dependent claims. As such, they incorporate by reference all of the limitations of their underlying base claims and intervening claims. The combination of Feldbrugge and Villagran fails to disclose each and every limitation incorporated by reference. Therefore, a *prima facie* case of obviousness has not been established with respect to these claims. Therefore, withdrawal of the rejection is respectfully requested.

3. Claims Rejected over the Combination of the
Feldbrugge and JP 58-282325 References

Claims 19-21, 74-76, and 116-118 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldbrugge taken together with JP 58-28235.

Feldbrugge has been described above. JP 58-282325 discloses preparation of a food product by blending a milk-protein-containing hydrous gel with a dehydrating agent (such as sodium chloride, calcium chloride, calcium lactate, a monosaccharide, an oligosaccharide, a sugar alcohol, an amino acid or salt thereof, or lecithin) and a powdery dispersant (such as dextrin, cellulose

powder, gum, white powder) under heating, followed by extruding and molding.

The combination of Feldbrugge and JP 58-28235 fails to make up for the deficiencies of the Feldbrugge reference alone. That is, claims 19-21, 74-76, and 116-118 are dependent claims. As such, they incorporate by reference all of the limitations of their underlying base claims and intervening claims. The combination of Feldbrugge and JP 58-28235 fails to disclose each and every limitation incorporated by reference. Therefore, a *prima facie* case of obviousness has not been established with respect to these claims. Therefore, withdrawal of the rejection is respectfully requested.

II. Response to Obviousness-type Double Patent Rejection

Claims 1-6, 13-26, 56-61, 68-82, and 109-119 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-44 of U.S. Patent No. 6,607,777.

Applicants respectfully submit herewith a Terminal Disclaimer signed by an official of the assignee. Applicants respectfully submit that this Terminal Disclaimer obviates the rejection. Withdrawal thereof is respectfully requested.

III. Conclusion

Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicant respectfully requests reconsideration and allowance of Claims 1-6, 13-26, 56-61, 68-82, and 109-119 and passage of this application to issue.

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Respectfully submitted,



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Enclosure: Terminal Disclaimer